

Claims

Sub B<sub>1</sub> 1. A pharmaceutical composition comprising a no more than sparingly water-soluble drug compound, a cyclodextrin, a physiologically tolerable water-soluble acid, and a physiologically tolerable water-soluble organic polymer.

2. The composition of claim 1 characterised in that the weight ratios of drug compound to acid and of drug compound to cyclodextrin are no more than 2:1.

10 3. The composition of claim 1 or 2 characterized in that the physical state of said composition is a glass thermoplastic phase.

Sub B<sub>2</sub> 4. The composition of claim 3 wherein the cyclodextrin is 2-hydroxypropyl- $\beta$ -cyclodextrin.

15 5. The composition of claim 3 wherein the acid is selected from the group comprising citric, fumaric, tartaric, maleic, malic, succinic, oxalic, malonic, benzoic, mandelic and ascorbic acid.

20 6. The composition of claim 5 wherein the acid is citric acid.

Sub B<sub>3</sub> 7. The composition of claim 3 wherein the polymer is selected from the group comprising

- alkylcelluloses such as methylcellulose,
- 25 - hydroxyalkylcelluloses such as hydroxymethylcellulose, hydroxyethylcellulose, hydroxypropylcellulose and hydroxybutylcellulose,
- hydroxyalkyl alkylcelluloses such as hydroxyethyl methylcellulose and hydroxypropyl methylcellulose,
- carboxyalkylcelluloses such as carboxymethylcellulose,
- 30 - alkali metal salts of carboxyalkylcelluloses such as sodium carboxymethylcellulose,
- carboxyalkylalkylcelluloses such as carboxymethylethylcellulose,
- carboxyalkylcellulose esters,
- starches,
- 35 - pectins such as sodium carboxymethylamylopectin,
- chitin derivatives such as chitosan,
- heparin and heparinoids,

- polysaccharides such as alginic acid, alkali metal and ammonium salts thereof, carrageenans, galactomannans, tragacanth, agar-agar, gum arabic, guar gum and xanthan gum,
- polyacrylic acids and the salts thereof,
- 5 - polymethacrylic acids and the salts thereof, methacrylate copolymers,
- polyvinylalcohol,
- polyvinylpyrrolidone, copolymers of polyvinylpyrrolidone with vinyl acetate,
- polyalkylene oxides such as polyethylene oxide and polypropylene oxide and copolymers of ethylene oxide and propylene oxide, e.g. poloxamers and
- 10 poloxamines.

8. The composition of claim 7 wherein the polymer has an apparent viscosity of 1 - 100 mPa.s when dissolved in a 2% aqueous solution at 20°C.

15 9. The composition of claim 8 wherein the polymer is hydroxypropylmethylcellulose.

*Sub by* 10. The composition of claim 3 wherein the drug is a basic compound.

20 11. A composition according to *claim 1* ~~any one of the preceding claims~~ that dissolves rapidly in body fluids, characterized in that it comprises from 50 to 95 % by weight of acid.

25 12. A composition according to *claim 1* ~~any one of the preceding claims~~ that provides sustained release of the drug, characterized in that it comprises a water soluble polymer having an apparent viscosity of more than 1,000 mPa.s when dissolved in a 2% aqueous solution at 20°C.

30 13. A pharmaceutical dosage form comprising a therapeutically effective amount of a pharmaceutical composition as defined in *claim 1* ~~any one of the preceding claims~~

14. The dosage form of claim 13 adapted for topical administration or administration into an externally voiding body cavity such as the nose, lungs, mouth, ear, stomach, rectum and vagina.

35 15. The dosage form of claim 13 wherein said composition is filled into a standard capsule, or alternatively is mixed with bulking agents and compressed into tablets.

16. The dosage form of claim 13, characterised in that at 5, 15 and 45 minutes after

addition of said dosage form to 0.1N hydrochloric acid at 37°C in the dissolution test set forth in USP test <711> in a USP-2 dissolution apparatus equipped with a paddle, from 7 to 25%, 45 to 70% and at least 96% respectively of drug is dissolved in said 0.1 N hydrochloric acid.

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17. A pharmaceutical composition according to any one of claims 1 to 12 or a pharmaceutical dosage form according to any one of claims 13 to 17 for use in a method of therapy or diagnosis of the human or non-human animal body.

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18. A pharmaceutical composition according to any one of claims 1 to 12 for use in the manufacture of a pharmaceutical dosage form for oral administration to a mammal in need of treatment, characterized in that said dosage form can be administered at any time of the day independently of the food taken in by said mammal.

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19. Use of a pharmaceutical composition according to any one of claims 1 to 12 for the manufacture of a pharmaceutical dosage form for oral administration to a mammal in need of treatment, characterized in that said dosage form can be administered at any time of the day independently of the food taken in by said mammal.

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20. A method of therapy or diagnosis of the human or non-human animal body which comprises administering to said body a therapeutically or diagnostically effective dose of a pharmaceutical composition according to ~~any one of claims 1 to 12~~ <sup>claim 1</sup>

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21. A pharmaceutical package suitable for commercial sale comprising a container, an oral dosage form as claimed in ~~any one of claims 12 to 17~~ <sup>claim 12</sup>, and associated with said package written matter non-limited as to whether the dosage form can be administered with or without food.